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| 09/605,213 | 06/28/2000 | Norbert Rahn | P00,1268 | 6581 |

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Schiff, Hardin & Waite
6600 Sears Tower
233 South Wacker Drive
Chicago, IL 60606

EXAMINER

MANTIS MERCADER, ELENI M

| ART UNIT | PAPER NUMBER |
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3737

DATE MAILED: 10/06/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/605,213

Applicant(s)

RAHN ET AL.

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-10, 15-22 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 3-10, 15-22 and 31-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

FINAL ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Response to Arguments

1. Applicant's arguments filed on 7/11/2003 have been fully considered but they are not persuasive with respect to claims 3-10, 15 and 31-33. The applicant argues in page 8, lines 16-19, that "[T]he distance of the tip of the needle from the image plane *itself*, therefore, is not specifically indicated in the displayed image, nor can it be concluded from viewing the displayed image." The claimed language does not include determining the distance of the tip of the needle from the image plane itself. The claimed language does not exclude determining the distance of the tip of the instrument from the target. Ferre et al.'980 clearly show designations of distance of the tip of the instrument from the target in the sagittal, axial and coronal 2D image planes. In other words, the current claim language does not exclude indications of distance of a probe from a 2D image plane of the target and if the tip is not located in the 2D image of the plane of the target mixing a designation of the distance into the 2D image, the designation of distance from the target. Therefore, the rejection is maintained.

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2. Applicant's arguments with respect to claims 16-22, referring to the creation of the 3D image have been considered but are moot in view of the new ground(s) of rejection. The introduction of "C-arm X-ray" constitutes new grounds of rejection. These claims are now rejected under Simon et al. '207.

3. The objections and 112 rejections were overcome. However, the amendment necessitates new grounds for objections of claims 18-20.

Claim Objections

4. Claims 18-19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 18 and 19 improperly depend from claim 16, as now claim 16 requires a C-arm X-ray imager.

5. Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 20 repeats the creation of a 3D image which was set forth in independent claim 16.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 15, 3-10 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paltieli'029 in view of Ferre et al.'980, both of record.

Paltieli'029 teaches all the features of the instant invention including: a system, a medical workstation, and a method comprising:

an image acquisition unit for acquiring image signals of a first subject an imaging unit for producing an image of the first subject from the image signals (see Figure 1, element 28, col. 6, lines 20-28);

a navigation system including a position acquisition system for determining a position of said image signal acquisition unit (see Figure 1, element 20; and col. 6, lines 29-40) and for determining a position of a second subject relative to said image acquisition unit (see Figure 1, element 32; and col. 6, lines 40-57);

a mixing unit for mixing a representation of said second subject into said image of said first subject (col. 7, lines 42-67 and col. 8, lines 1-63; also see Figures 7-10).

Paltieli'029 teaches a navigation system including identifiers, selected from the group consisting of detectable marks and position sensors, which are respectively attachable to said image signal acquisition unit and to said second subject and which are identifiable as to position by said position acquisition unit (see Figures 1 and 4; in Figure 4, elements 60 and 62; also see col. 6, lines 66-67 and col. 7, lines 1-18).

Paltieli'029 teaches the image signal acquisition unit which comprises an ultrasound probe (Figure 1, element 28; col. 6, lines 23-27).

Paltieli'029 teaches the image signal acquisition unit comprising an X-ray source and an X-ray receiver (see Figure 2, elements 42 and 40; and col. 6, lines 58-65).

Paltieli'029 teaches the imaging unit producing a 3D image of said first subject from said image signals (col. 8, lines 32-63).

Paltieli'029 teaches the imaging unit producing a 2D image of said first subject from said image signals (col. 8, lines 20-31) and wherein the mixing unit mixes an indication of a distance of the second subject from the image plane into the 2D image (see Figures 7-10; in Figure 8 see screen 106, indicating needle 92 on ultrasound image 108; also see col. 8, lines 11-32).

Paltieli'029 teaches the position acquisition unit simultaneously identifies the position of said image signal acquisition unit and the position of the second subject and indicating a projection of the tip into the 2D image as indicated by the dotted line (see Figures 4 and 7; and col. 6, lines 66-67 and col. 7, lines 1-67).

Paltieli'029 teaches an acceptance device for the first subject and wherein the position acquisition device identifies a position of the acceptance device simultaneously with identifying the position of the image signal acquisition unit and the position of the second subject (the verification computer unit constitutes such a device for verifying needle insertion based on positions of the subject based on the ultrasound image and the target; see col. 9, lines 46-63).

Paltieli'029 does not teach a mixing unit connected to the imaging unit for mixing a representation of said tip into said 2D image and if the said tip is not located in said image plane, for mixing a designation of the distance of the tip from the image plane into the 2D image said designation being alterable and indicating a magnitude of said distance.

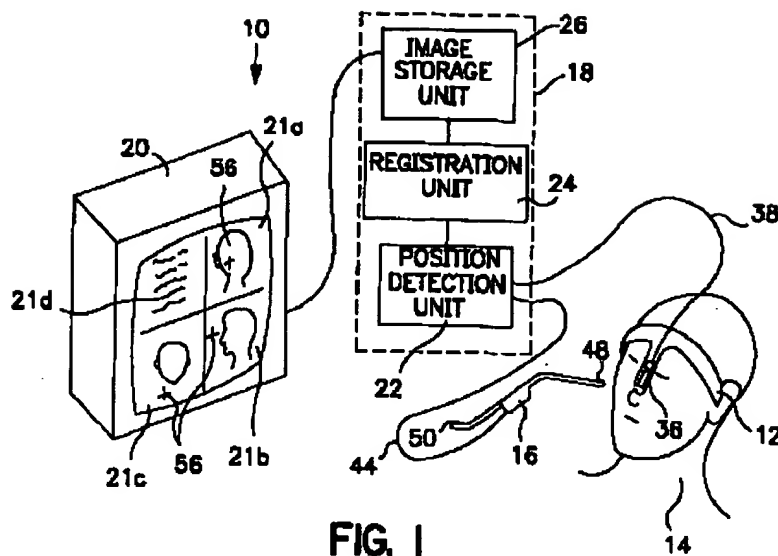


FIG. 1

Figure 1 of Ferre et

al. '980 indicates the alterable position of the instrument with respect to its distance from the patient as displayed on the image, indicated in 21a, or outside of the image as indicated in 21b or 21c by element 56

In the same field of endeavor, Ferre et al. '980 teach in stereotactic systems utilization of a mixing unit for creating a composite image of the location of the tip as well as the tube of an instrument (see col. 5, lines 28-42). Ferre et al. '980 further teach mixing a representation of the tip in the 2D image as indicated in Figure 1, as displayed by "x" in coronal image 21a, wherein the position of the tip 56 is located into the 2D image. Ferre et al. '980 further teach that if the tip 56 is not located in the image plane but a distance away, mixing a designation of the distance of the tip from the image plane into the 2D image, notice in particular the sagittal image plane 21b and the axial image plane 21c of Figure 1, both indicating that the tip 56 is not located in the image plane but a distance away, and mixing a designation of the distance of the tip namely by using "x" indicated as element 56 which itself indicates the magnitude of distance from the 2D image. These positions are alterable by movement of the instrument as this is a localizing system tracking the position of the tip (col. 5, lines 28-42).

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It would have been obvious to one skilled in the art at the time that the invention was made to have modified Paltieli'029 and incorporated the teaching of Ferre et al.'980 to allow for better position monitoring of the instrument while in surgery in different imaging planes.

8. Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paltieli'029 in view of Ferre et al.'980 as applied to claim 15 above, and further in view of Manwaring et al.'819.

Regarding claim 32, Paltieli'029 in view of Ferre et al.'980 teach all the features of the instant invention except for the teaching of using a circle having a diameter, which is alterable according to the magnitude of the distance. Manwaring et al.'819 teach using a circle having a diameter, which is alterable according to the magnitude of the distance (col. 10, lines 23-25; referring to distance-to-target feature circle 126 changing according to the distance of the probe tip from the target). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Paltieli'029 in view of Ferre et al.'980 and incorporated the teaching of Manwaring et al.'819 to incorporate the distance-to-target feature circle 126 and superimpose this feature to all of the planes of interest, sagittal, coronal and axial to further assist the operator in determining how far the tip of the probe is from the target of interest as related to all of the planes of interest.

Regarding claim 33, Paltieli'029 in view of Ferre et al.'980 teach all the features of the instant invention except for the teaching of using color to guide the instrument. Manwaring et al.'819 teach using different colors in the 4 quadrants to further guide targeting the instrument (col. 8, lines 25-44). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Paltieli'029 in view of Ferre et al.'980 and

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incorporated the teaching of Manwaring et al.'819 in order to easily determine the location of the instrument and its distance to target by using the different colors to further assist in localizing the instrument.

9. Claims 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al.'207 in view of Cosman'072, of record.

Simon et al.'207 teach all the features of the current invention including a C-arm X-ray image signal acquisition unit for producing a 3D image of a first subject, a position acquisition system for determining the position of the C-arm X-ray acquisition imager and a second subject such as a surgical instrument and a mixing unit for mixing a representation of the second unit into the 3D image as it relates to the acquisition system (see Figure 1 and see col. 14, lines 5-67; col. 15, lines 1-30; col. 5, lines 30-67; and col. 6, lines 1-63).

Simon et al.'207 do not teach localization of the support mechanism.

In the same field of endeavor, Cosman'072 teaches an optical tracking system to track and coordinate the treatment device (LINAC), the ultrasound imager, the patient and the couch/bed/or support as indicated in Figures 1 and 7 (see col. 8, lines 43-55 and col. 14, lines 20-42). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Simon et al.'207 and incorporated the teaching of Cosman'072 to track all of the elements of the system relative to each other in order to more accurately guide treatment and adjust treatment when the patient moves (see for motivation to combine col. 2, lines 13-37, describing need for determining the positional relationships of the elements of the system to effectuate accurate treatment).

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Conclusion

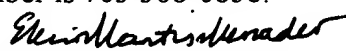
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on 703 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.


Eleni Mantis Mercader
Patent Examiner
Art Unit 3737

EMM